4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-D-0548]

Data Standards for Drug and Biological Product Submissions Containing Real-World Data; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled "Data Standards for Drug and Biological Product Submissions Containing Real-World Data." This guidance provides recommendations to sponsors to help support compliance with the Federal Food, Drug, and Cosmetic Act (FD&C Act) when submitting study data derived from real-world data (RWD) sources in applicable regulatory submissions using standards specified in the Data Standards Catalog (Catalog). FDA is publishing this draft guidance as part of a series of guidance documents under its program to evaluate the use of real-world evidence (RWE) in regulatory decision making.

DATES: Submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your

comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2021-D-0548 for "Data Standards for Drug and Biological Product Submissions Containing Real-World Data." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information

you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002, or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in

processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Dianne Paraoan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave, Bldg. 51, Rm. 3326, Silver Spring, MD 20993-0002, 301-796-3161, Dianne.Paraoan@fda.hhs.gov, or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Data Standards for Drug and Biological Product Submissions Containing Real-World Data." Under section 745A(a) of the FD&C Act (21 U.S.C. 379k-1(a)) and the guidance for industry entitled "Providing Regulatory Submissions in Electronic Format – Standardized Study Data" (Study Data Guidance), clinical or nonclinical study data contained in new drug applications (NDAs), abbreviated new drug applications (ANDAs), certain biologics license applications (BLAs), and certain investigational new drug applications (INDs) must be in an electronic format that the Agency can process, review, and archive, unless such submission is exempt from the electronic submission requirements or if FDA has granted a waiver. This guidance clarifies that RWD submitted as study data in NDAs, ANDAs, certain BLAs, and certain INDs are subject to the requirements in section 745A(a) of the FD&C Act (21 U.S.C. 379k-1(a)) and the Study Data Guidance. Currently, as stated in the Study Data Guidance, the Agency can process, review, and archive electronic submissions of clinical and nonclinical study data (including data derived from RWD sources) that use the standards specified in the Catalog posted to FDA's Study Data Standards Resources webpage (https://www.fda.gov/industry/fda-resources-data-standards/study-data-standards-resources). Therefore, submissions subject to section 745A(a) of the FD&C Act that contain study data derived from RWD sources must be in electronic format

using the study data standards currently supported by FDA as specified in the Catalog. This guidance provides recommendations to sponsors for complying with section 745A(a) of the FD&C Act when submitting study data derived from RWD sources in an applicable regulatory submission using standards specified in the Catalog.

Section 3022 of the 21st Century Cures Act (Cures Act) amended the FD&C Act to add section 505F, Utilizing Real World Evidence (21 U.S.C. 355g). This section requires the establishment of a program to evaluate the potential use of RWE to help support the approval of a new indication for a drug approved under section 505(c) of the FD&C Act (21 U.S.C. 355(c)) and to help support or satisfy postapproval study requirements. This section also requires that FDA use the program to inform guidance for industry on the circumstances under which sponsors of drugs may rely on RWE and the appropriate standards and methodologies for collection and analysis of RWE submitted to evaluate the potential use of RWE for those purposes. Further, under the Prescription Drug User Fee Amendments of 2017 (PDUFA VI), FDA committed to publishing draft guidance on how RWE can contribute to the assessment of safety and effectiveness in regulatory submissions. FDA is issuing the draft guidance entitled "Data Standards for Drug and Biological Product Submissions Containing Real-World Data" as part of a series of guidance documents to satisfy the Cures Act mandate and the PDUFA VI commitment.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on "Data Standards for Drug and Biological Product Submissions Containing Real-World Data." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 314 (Applications for FDA Approval to Market a New Drug) have been approved under OMB control number 0910-0001; the collections of information in 21 CFR part 312 (Investigational New Drug Regulations) have been approved under OMB control number 0910-0014; the collections of information in 21 CFR part 58 (Good Laboratory Practice Regulations for Nonclinical Laboratory Studies) have been approved under OMB control number 0910-0119; and the collections of information in 21 CFR part 601 (General Licensing Provisions: Biologics License Application, Changes to an Approved Application, Labeling, Revocation and Suspension) have been approved under OMB control number 0910-0338.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at https://www.fda.gov/regulatory-information/search-fda-guidance-documents, https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, or https://www.regulations.gov.

Dated: October 8, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

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